



**Australian Government**  
**National Health and Medical Research Council**

# Application of the *Guidelines under Section 95 of the Privacy Act 1988 (2014)*

## Background

The [\*Guidelines under Section 95 of the Privacy Act 1988\*](#) (s95 Guidelines) provide a framework for the conduct of medical research using information held or collected by agencies where personal information needs to be used and where it is not practicable to obtain the individual's consent. In these situations, an agency may collect, use or disclose records containing personal information for medical research purposes without breaching the Privacy Act if the proposed medical research has been approved by a properly constituted Human Research Ethics Committee (HREC) in accordance with the s95 Guidelines.

This form provides a template for researchers and HRECs to satisfy the data custodian that the s95 Guidelines have been appropriately applied and provide evidence that the HREC has the necessary qualifications and/or experience to consider privacy issues.

This template can be manipulated to suit the purposes of any Commonwealth agency which acts as a data custodian.

## Instructions

This form should be accompanied by the HREC application and proof of the HREC decision.

**Part A** – to be completed by the responsible researcher

**Parts B and C** – to be completed by the approving HREC Chairperson

Both the researcher and the Chairperson are required sign the declaration at **Part D**.

## Disclaimer

**Submission of this form does not guarantee release of the data.** In accordance with paragraph 1.3 of the s95 Guidelines, agencies can decide to decline to disclose personal information for use in medical research even where the medical research has been approved by an HREC in accordance with these guidelines.

## Part A – Breach of one or more APPs

### Researcher to complete

**Q.1:** Under paragraph 2.3 of the s95 Guidelines, when research may involve a breach of one or more APPs, the proposal for that research to be submitted to an HREC must contain a reference to the APP(s) and must also state reasons for believing that the public interest in the research outweighs, to a substantial degree, the public interest in complying with the APP(s). **Please identify the APPs which may be breached by the proposed research and provide your reasons below:**

☐ **APP1 - open and transparent management of personal information**

Reason(s)

☐ **APP2 — anonymity and pseudonymity**

Reason(s)

☐ **APP3 — collection of solicited personal information**

Reason(s)

☐ **APP4 — dealing with unsolicited personal information**

Reason(s)

☐ **APP5 — notification of the collection of personal information**

Reason(s)

☐ **APP6 — use or disclosure of personal information**

Reason(s)

☐ **APP7 — direct marketing**

Reason(s)

☐ **APP8 — cross-border disclosure of personal information**

Reason(s)

☐ **APP9 — adoption, use or disclosure of government related identifiers**

Reason(s)

☐ **APP10 — quality of personal information**

Reason(s)

☐ **APP11 — security of personal information**

Reason(s)

☐ **APP12 — access to personal information**

Reason(s)

☐ **APP13 — correction of personal information**

Reason(s)

## Part B – HREC Expertise

### HREC Chairperson to complete

**Q.2:** Before making a decision under the s95 Guidelines, the HREC must assess whether it has sufficient information, expertise and understanding of privacy issues, either amongst the members of the HREC or otherwise available to it, to make a decision that takes proper account of privacy (refer to paragraph 3.1 of the s95 Guidelines). **Please provide details of the HREC's qualifications and/or experience to consider privacy issues below:**

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## Part C – Weighing the public interest

### HREC Chairperson to complete

The HREC must ensure that the committee has the competence to determine if the public interest in the proposed research outweighs, or does not outweigh, to a substantial degree, the public interest in the protection of privacy (refer to Section 3 of the s95 Guidelines).

Has the HREC considered:

- (a) the degree to which the medical research is likely to contribute to: Y ☐ N ☐
- the identification, prevention or treatment of illness or disease
  - scientific understanding relating to health
  - the protection of the health of individuals and/or communities
  - the improved delivery of health services
  - scientific understanding or knowledge
- (b) any likely benefits to individuals, to the category of persons to which they belong, or the wider community that will arise from the medical research being undertaken in the manner proposed Y ☐ N ☐
- (c) whether the medical research design can be satisfied without risking infringement of an APP and the scientific defects in the medical research that might arise if the medical research was not conducted in the manner proposed Y ☐ N ☐
- (d) the financial costs of not undertaking the medical research (to government, the public, the health care system, etc.) Y ☐ N ☐
- (e) the public importance of the medical research Y ☐ N ☐
- (f) the extent to which the data being sought are ordinarily available to the public from that agency Y ☐ N ☐
- i. whether the medical research involves use of data in a way which is inconsistent with the purpose for which the data was made public
  - ii. whether the medical research requires an alteration of the format of the data of a kind that would, if used by an agency, involve a breach of an APP
- g) whether the risk of harm to a person whose personal information is to be used in proposed research is minimal, having regard to the elements of that research provided in response to paragraph 2.3 of these guidelines Y ☐ N ☐
- h) the standards of conduct that are to be observed in medical research, including: Y ☐ N ☐
- i. the study design and the scientific credentials of the researchers
  - ii. if the research involves contact with participants, the procedures or controls which will apply to ensure that participants are treated with integrity and sensitivity, including whether questions to be asked or procedures to be

employed are intrusive

- iii. whether access to personal information is restricted to appropriate researchers
- iv. the risk that a person or group could be identified in the published results
- v. the procedures that are to be followed at the completion of the research to ensure that all data containing personal information are at least as secure as they were in the sources from which the data were obtained, including the date when the data will be destroyed or returned.

## Part D – Declaration

By signing below, the researcher and HREC Chairperson are making the declaration that the information provided in this form is true and correct.

### Researcher

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Print name

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Signature

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Date

### HREC Chairperson

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Print name

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Signature

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Date

TEMPLATE